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(54) **CEMENT MIXER AND BONE FILLER
DEVICE**

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See application file for complete search history.

(56) **References Cited**

U.S. PATENT DOCUMENTS

3,534,734 A * 10/1970 Budreck 604/194
3,618,603 A * 11/1971 Levenson 604/229

5,085,638 A * 2/1992 Farbstein et al. 604/110
5,114,405 A * 5/1992 Winter 604/110
5,149,323 A * 9/1992 Colonna 604/110
5,156,606 A * 10/1992 Chin 606/86 R
5,320,603 A * 6/1994 Vetter et al. 604/82
5,368,386 A 11/1994 Murray
5,383,864 A * 1/1995 van den Heuvel 604/218
5,496,285 A * 3/1996 Schumacher et al. 604/218
5,514,135 A 5/1996 Earle

(Continued)

FOREIGN PATENT DOCUMENTS

EP 1466572 A2 10/2004
JP 2001218774 A 8/2001
WO 2009105905 A1 9/2009

OTHER PUBLICATIONS

International Search Report and Written Opinion for PCT/US2013/022859 the counterpart application mailed on May 15, 2013.

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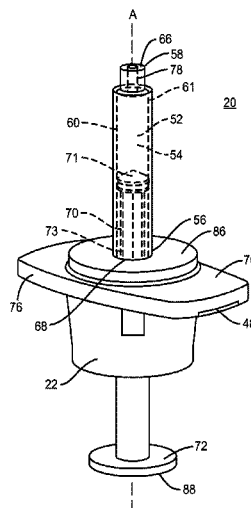
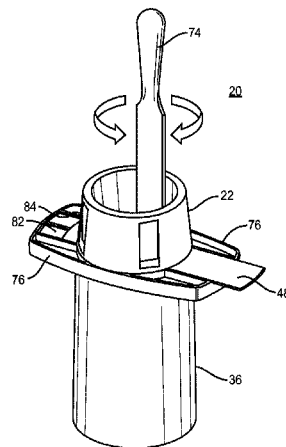
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ABSTRACT

An apparatus and method for mixing and dispensing bone cement is provided. The apparatus includes a mixing vessel for mixing bone cement attached to a syringe body. The syringe body having a lumen that is connected to the mixing vessel by a passageway between the mixing vessel and the lumen of the syringe body. A separator is provided between the mixing vessel and the syringe body and includes an orifice therein so that when the opening in the separator is misaligned with the lumen the passageway is blocked and when aligned the passageway is continuous with the lumen so that bone cement can pass into the syringe body. A plunger is provided and is slideably movable along the longitudinal axis of the syringe body so as to advance the bone cement out of the distal end of the syringe.

19 Claims, 4 Drawing Sheets



(56)

References Cited

U.S. PATENT DOCUMENTS

5,558,136	A	9/1996	Orrico		7,744,270	B2	6/2010	Plishka et al.	
5,674,195	A *	10/1997	Truthan	604/87	7,946,417	B2	5/2011	Plishka et al.	
6,083,229	A	7/2000	Constantz et al.		8,021,037	B2	9/2011	Krueger et al.	
6,149,655	A	11/2000	Constantz et al.		2006/0189958	A1	8/2006	Talton et al.	
6,767,335	B1 *	7/2004	Helg	604/110	2008/0065027	A1 *	3/2008	Sharp	604/220
					2010/0292672	A1 *	11/2010	Lee	604/518
					2011/0264052	A1 *	10/2011	Oliver	604/218

* cited by examiner

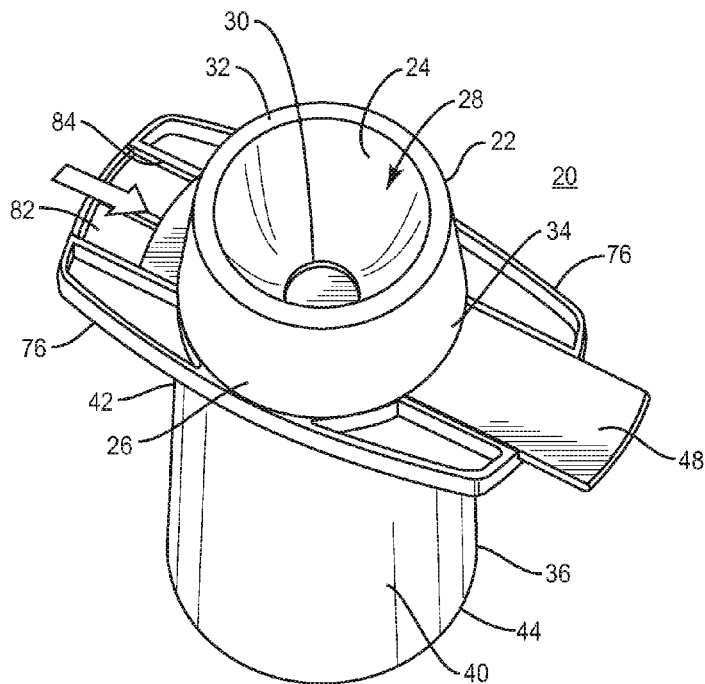


FIG. 1

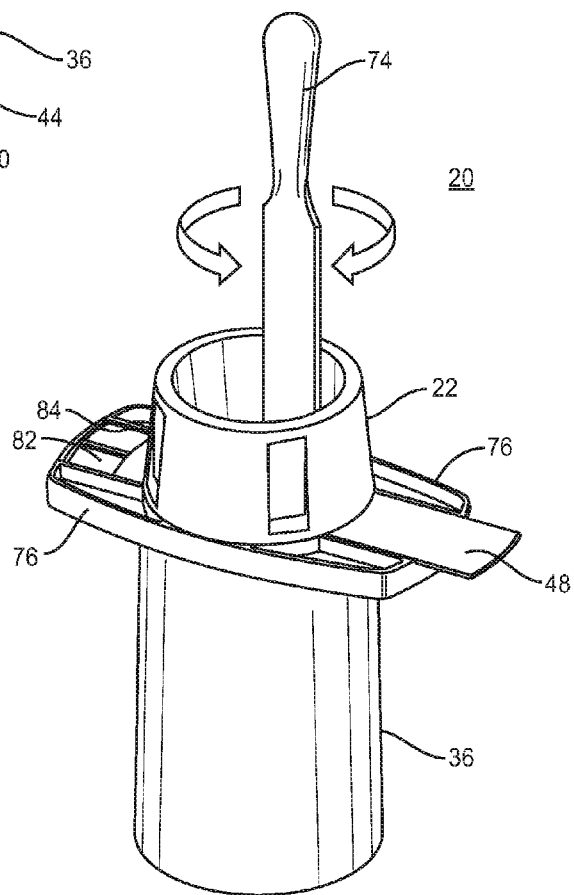


FIG. 2

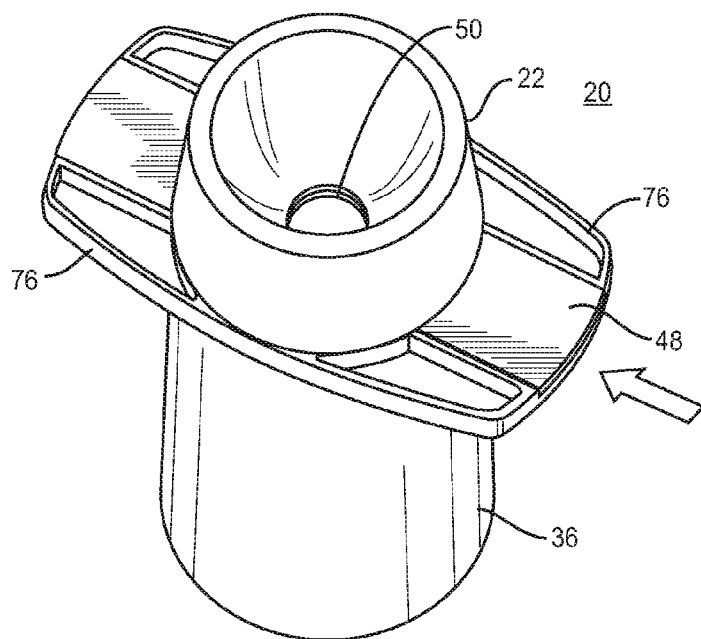


FIG. 3

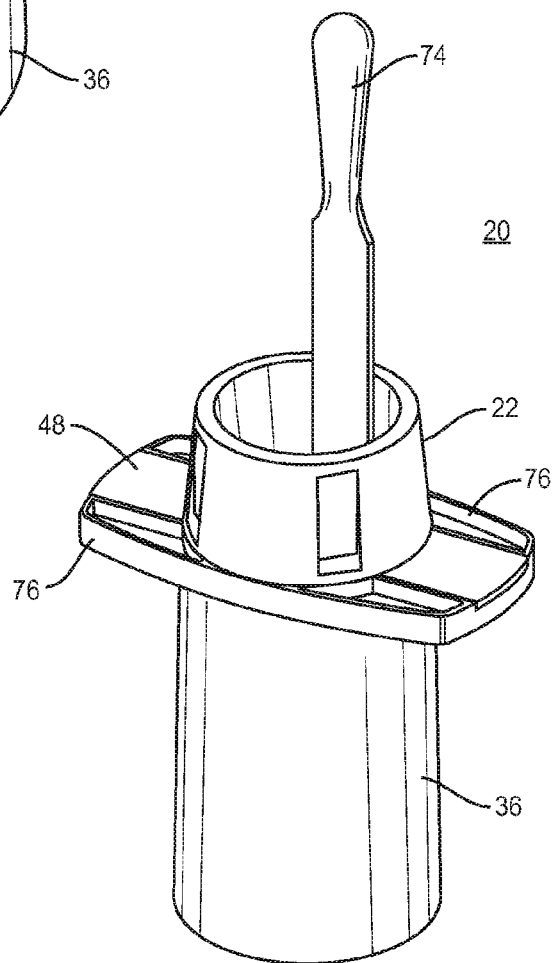


FIG. 4

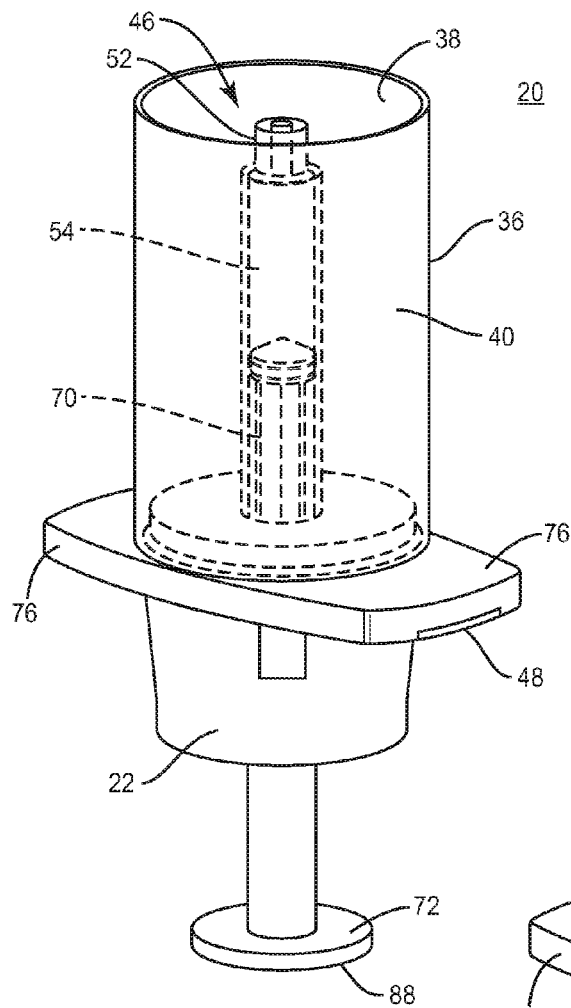


FIG. 5

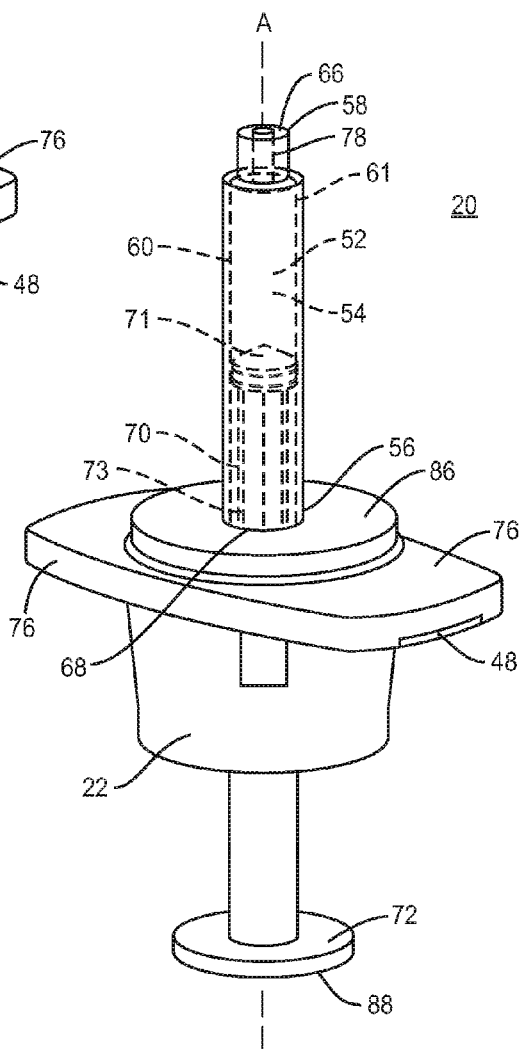


FIG. 6

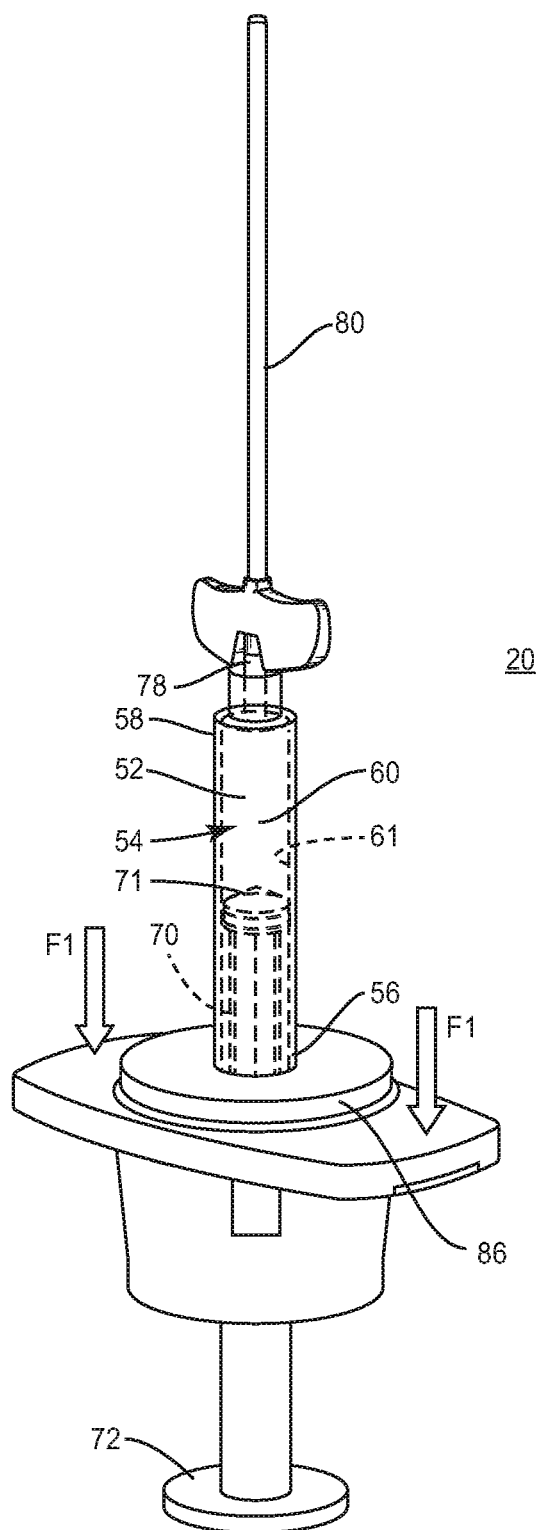


FIG. 7

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**CEMENT MIXER AND BONE FILLER
DEVICE**

TECHNICAL FIELD

The present invention relates to devices and methods for mixing curable materials for use with stabilizing bone structures. More particularly, it relates to devices, systems and methods for mixing the components that form the curable materials.

BACKGROUND

Vertebral compression fracture (VCF) can occur when a vertebral body is too weak to support a load and the spine collapses. A VCF may cause the spine to shorten, leading to spinal deformities and altering spinal biomechanics. Collapse may result in thoracic and lumbar spinal deformity and is often seen in elderly people. The spinal deformity, commonly known as a Dowager's Hump, is also referred to as kyphosis. Several causes can lead to a VCF, including osteoporosis, cancer or a traumatic incident, such as a fall or car accident.

A treatment for a VCF can involve injecting a material into vertebra, either at low or high pressure. Optionally, a surgical balloon can first be inserted into a vertebra and expanded to restore a collapsed vertebra to its original shape. A material can then be inserted into the restored vertebra, which, upon hardening, can maintain the original shape of the vertebra. The technique of inserting a material into a cavity, such as a collapsed vertebra, can also be used to treat other medical conditions, for example, in knee or hand joints.

Surgeons commonly use bone cement in order to fill voids in bone. It is desirable to use bone cement, such as an adhesive bone cement, to hold small bone fragments in place to allow for healing, when methods such as traditional plate and screw methods of reattachment are not feasible. Only a small amount of bone cement may be required to fill small gaps between the bone fragments in order to glue the fragments together. For example, volumes of cement under one cubic centimeter may be used. In such applications, the cement material may be delivered to the repair site through a delivery system, such as a syringe having a cannulated needle.

The bone cement may be a mixture of different ingredients, and, before applying the bone cement to a repair site, the cement may be prepared by mixing it in a bowl with a pestle. Prepared bone cements can have various viscosities, and some may have quite a high viscosity, with a consistency like a tacky paste. For example, typical adhesive bone cement may have a viscosity greater than 80 Pascal-seconds. The prepared bone cement can be transferred to the syringe through the opening in the proximal end of the syringe, which is made accessible by removing the plunger from the syringe.

The prepared cement material can be difficult to pour into the proximal end of an application syringe, especially when it has a high viscosity. Additionally, the opening at the proximal end of the syringe may be quite small, thus making the pouring of the bone cement into the syringe even more difficult. The pouring of the bone cement into the proximal end of the syringe can also be time consuming, which can be problematic when the curing time for the cement is relatively short. Furthermore, the material that is poured into the proximal end of the syringe can develop air pockets along the syringe barrel. Air pockets can detrimentally cause pressure spikes during injection of the cement. These pressure increases can cause filter pressing, where the liquid portion of the cement separates from the powder portion. This can result in the

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liquid being squeezed out of the syringe, leaving behind a dense mass of powder, which can jam the syringe.

SUMMARY

This application relates to an apparatus for mixing and delivering bone cement and a method for filling a cavity in a patient's body with bone cement. The apparatus includes a mixing vessel for mixing the first and second materials to prepare the bone cement for delivery. A syringe body is attached to the mixing vessel. The syringe body defines a lumen and a longitudinal axis extending from a proximal end to an oppositely disposed distal end of the syringe body. Each of the proximal and distal ends having an opening therein. The openings in the syringe body are alignable with the orifice in the mixing vessel so as to provide a passageway between the mixing vessel and the lumen of the syringe body. A separator is provided between the mixing vessel and the proximal end of the syringe body. The separator includes an orifice therein. The separator is configured to slide between a first position wherein the orifice of the separator substantially aligns with the orifice in the mixing vessel and the passageway to a second position wherein the opening in the separator is misaligned so as to block the passageway between said mixing vessel and the passageway. When the separator is in the first position, the bone cement is transferred from the mixing vessel through the lumen to a dispensing structure. A plunger is provided and is configured to fit into the opening in the passageway between said mixing vessel and the lumen of the syringe body. The plunger is slideably movable along the central axis toward the distal end of the syringe body to facilitate movement of the bone cement into the dispensing structure.

A kit including one or all of the components of the bone cement mixing apparatus is provide, such as for example, a disposable, peel-pack, pre-packed sterile devices. The kit can also be provided in a sterilized or in the alternative be provided in a sterilizable packaging. The kit includes, at least one of the following: syringe body, mixing vessel, separator, plunger, base and dispensing structures. The syringes and dispensing structures can be of various sizes, gauges and types depending on the particular application. One or all of the components of the bone cement mixing apparatus may be reusable and sterilizable. The bone mixing apparatus may be configured as a kit with multiple sized and configured components.

The method of using the apparatus includes attaching a mixing vessel to a syringe body including a lumen and defining a passageway. A separator is positioned in a second position, where its orifice is not aligned with the orifice of the mixing vessel. A base can be attached to provide an easier gripping surface for holding the apparatus. Bone cement materials are place inside mixing vessel and are mixed thoroughly with a spatula. Once bone cement materials are thoroughly mixed, the separator is shifted to the first position where its orifice is aligned with the orifice of the mixing vessel and then passageway. The spatula is used to push and guide the bone cement mixture into the syringe body. A plunger is placed into the passageway of the syringe body through the orifices of the separator and the mixing vessel and is pushed towards the distal end of the syringe body. The apparatus is flipped over so that the handle of the plunger rests on table or other surface. If a base was attached, it can now be removed. A dispensing structure is attached the syringe body. A force can be applied to flanges to push the bone cement

material into the dispensing structure. A plurality of dispensing structures can be filled one after another as needed for the particular use.

BRIEF DESCRIPTION OF THE DRAWINGS

The present disclosure will become more readily apparent from the specific description accompanied by the following drawings, in which:

FIG. 1 is a perspective view of one particular embodiment of a system in accordance with the principles of the present disclosure;

FIG. 2 is a perspective view of components system shown in FIG. 1 where the separator is in a second position;

FIG. 3 is a perspective view of components of the system shown in FIG. 1 where the separator is in a first position;

FIG. 4 is a perspective view of components of the system shown in FIG. 1 including a spatula;

FIG. 5 is a perspective view of components of the system shown in FIG. 1 turned upside down and including the plunger;

FIG. 6 is a perspective view of components of the system shown in FIG. 5;

FIG. 7 is a perspective view of components of the system shown in FIG. 1 including a dispensing structure;

Like reference numerals indicate similar parts throughout the figures.

DETAILED DESCRIPTION

An apparatus and method is described for injecting a material into a cavity in a patient's body. For illustrative purposes, the apparatus and method shall be described in the context of injecting a bone filling cement into a vertebra of a patient to treat kyphosis, although the apparatus and methods can be used to treat other conditions.

The present disclosure may be understood more readily by reference to the following detailed description of the disclosure taken in connection with the accompanying drawing figures, which form a part of this disclosure. It is to be understood that this disclosure is not limited to the specific devices, methods, conditions or parameters described and/or shown herein, and that the terminology used herein is for the purpose of describing particular embodiments by way of example only and is not intended to be limiting of the claimed disclosure. Also, as used in the specification and including the appended claims, the singular forms "a," "an," and "the" include the plural, and reference to a particular numerical value includes at least that particular value, unless the context clearly dictates otherwise. Ranges may be expressed herein as from "about" or "approximately" one particular value and/or to "about" or "approximately" another particular value. When such a range is expressed, another embodiment includes from the one particular value and/or to the other particular value. Similarly, when values are expressed as approximations, by use of the antecedent "about," it will be understood that the particular value forms another embodiment. It is also understood that all spatial references, such as, for example, horizontal, vertical, top, upper, lower, bottom, left and right, are for illustrative purposes only and can be varied within the scope of the disclosure. For example, the references "upper" and "lower" are relative and used only in the context to the other, and are not necessarily "superior" and "inferior".

Further, as used in the specification and including the appended claims, "treating" or "treatment" of a disease or condition refers to performing a procedure that may include

administering one or more drugs to a patient (human, normal or otherwise or other mammal), in an effort to alleviate signs or symptoms of the disease or condition. Alleviation can occur prior to signs or symptoms of the disease or condition appearing, as well as after their appearance. Thus, treating or treatment includes preventing or prevention of disease or undesirable condition (e.g., preventing the disease from occurring in a patient, who may be predisposed to the disease but has not yet been diagnosed as having it). In addition, treating or treatment does not require complete alleviation of signs or symptoms, does not require a cure, and specifically includes procedures that have only a marginal effect on the patient. Treatment can include inhibiting the disease, e.g., arresting its development, or relieving the disease, e.g., causing regression of the disease. For example, treatment can include reducing acute or chronic inflammation; alleviating pain and mitigating and inducing re-growth of new ligament, bone and other tissues; as an adjunct in surgery; and/or any repair procedure. Also, as used in the specification and including the appended claims, the term "tissue" includes soft tissue, ligaments, tendons, cartilage and/or bone unless specifically referred to otherwise.

The following discussion includes a description of bone cement mixing apparatus and related methods of employing the apparatus in accordance with the principles of the present disclosure. Alternate embodiments are also disclosed. Reference will now be made in detail to the exemplary embodiments of the present disclosure, which are illustrated in the accompanying figures. Turning now to FIGS. 1-7, there is illustrated components of a bone cement mixing apparatus 20 in accordance with the principles of the present disclosure.

The components of bone cement mixing apparatus 20 can be fabricated from biologically acceptable materials suitable for medical applications, including metals, synthetic polymers, ceramics and bone material and/or their composites, depending on the particular application and/or preference of a medical practitioner. For example, the components of bone cement mixing system 20, individually or collectively, can be fabricated from materials such as stainless steel alloys, commercially pure titanium, titanium alloys, Grade 5 titanium, super-elastic titanium alloys, cobalt-chrome alloys, stainless steel alloys, superelastic metallic alloys (e.g., Nitinol, super elasto-plastic metals, such as GUM METAL® manufactured by Toyota Material Incorporated of Japan), ceramics and composites thereof such as calcium phosphate (e.g., SKEL-ITE™ manufactured by Biologix Inc.), thermoplastics such as polyaryletherketone (PAEK) including polyetheretherketone (PEEK), polyetherketoneketone (PEKK) and polyetherketone (PEK), carbon-PEEK composites, PEEK-BaSO₄, polymeric rubbers, polyethylene terephthalate (PET), fabric, silicone, polyurethane, silicone-polyurethane copolymers, polymeric rubbers, polyolefin rubbers, hydrogels, semi-rigid and rigid materials, elastomers, rubbers, thermoplastic elastomers, thermoset elastomers, elastomeric composites, rigid polymers including polyphenylene, polyamide, polyimide, polyetherimide, polyethylene, epoxy, bone material including autograft, allograft, xenograft or transgenic cortical and/or corticocancellous bone, and tissue growth or differentiation factors, partially resorbable materials, such as, for example, composites of metals and calcium-based ceramics, composites of PEEK and calcium based ceramics, composites of PEEK with resorbable polymers, totally resorbable materials, such as, for example, calcium based ceramics such as calcium phosphate, tri-calcium phosphate (TCP), hydroxyapatite (HA)-TCP, calcium sulfate, or other resorbable polymers such as polyaetide, polyglycolide, polytyrosine carbonate, polycaprolactone and their combinations.

Various components of bone cement mixing system **20** may have material composites, including the above materials, to achieve various desired characteristics such as strength, rigidity, elasticity, compliance, biomechanical performance, durability and radiolucency or imaging preference. The components of bone cement mixing system **20**, individually or collectively, may also be fabricated from a heterogeneous material such as a combination of two or more of the above-described materials. The components of bone cement mixing system **20** may be monolithically formed, integrally connected or include fastening elements and/or instruments, as described herein.

In one embodiment, as shown in FIGS. 1-7, a bone cement mixing apparatus **20** is provided. Bone cement mixing apparatus **20** includes a mixing vessel **22** for mixing first and second materials to make bone cement. The first and second materials are used to fill bone cavities. Examples of cavity filling material include: bone cement (e.g., polymethyl methacrylate (PMMA) cement, ceramics); human bone graft (e.g., autograft, allograft); and synthetic derived bone substitutes (e.g., calcium sulfate, calcium phosphate, hydroxyapatite). Cavity filling materials can be supplemented with other therapeutic substances, e.g., antibiotics, growth factors and chemotherapeutic agents.

Bone cement mixing apparatus **20** includes a mixing vessel **22** having an inner surface **24** and an outer surface **26**. Outer surface **26** extends between a first end **32** and a second end **34**. Inner surface **24** forms a cavity, such as, for example, a bowl **28** for disposal and mixing of first and second materials. It is contemplated that mixing vessel **28** be round, oval, oblong, square, rectangular, polygonal, irregular, uniform, non-uniform, offset, staggered, tapered, consistent or variable, depending on the requirements of a particular application. Inner surface **24** includes an orifice **30** disposed at the second end **34**. It is contemplated that orifice **30** be round, oval, oblong, square, rectangular, polygonal, irregular, uniform, non-uniform, offset, staggered, tapered, consistent or variable, depending on the requirements of a particular application.

Bowl **22** includes flanges **76** that extend outward from outer surface **26** of bowl **22** and transverse to central axis A. Flanges **76** provide a surface for applying a force F to advance a plunger **70** into the passageway, as discussed below. Flanges **76** include a channel **82** disposed therein. Channel **82** is configured as a track **84** accept disposal of separator **48**, as discussed below. Flanges **76** include a coupling portion **86** configured to removably couple a base **36** discussed below to bowl **22**.

A syringe body **52** is attached to second end **34** of bowl **22**. Syringe body **52** includes a proximal end **56** and a distal end **58**. Syringe body **52** defines a chamber **54** extending between proximal end **56** and distal end **58** along a central axis A. It is contemplated that syringe body be round, oval, oblong, uniform, or tapered depending on the requirements of a particular application. Syringe **52** includes a lumen **60** disposed therein. Lumen **60** includes an inner surface **61**. Lumen **60** extends through syringe body **52** from proximal end **56** to the oppositely disposed distal end **58** along axis A. Proximal end **56** includes an opening **66**. Distal end includes **58** an opening **68**. Openings **66** and **68** align with orifice **30** to provide a passageway between bowl **22** and lumen **60**.

Distal end **56** further includes a coupling portion **78** adapted to attach to at least one dispensing structure **80**. It is contemplated that dispensing structure **80** can be a cannula, a needle, a cannulated needle or a syringe needle. Second end **58** includes a coupling portion, not shown, for attachment and

detachment of bowl **22**. This allows for use of more than one or various sized syringe bodies or multiple bowls.

To allow for movement of the bone cement between bowl **22** and syringe body **52** a separator **48** is disposed between bowl **22** and syringe body **52**. Separator **48** slides along track **84** disposed in channel **82**. Movement of separator **48** allows separator to move from a first position to a second position along track **84**. Separator **48** includes an orifice **50** that aligns with orifice **30** and passageway in its first position. Separator **48** is configured to slide between proximal end **56** of the syringe body **52** and bowl **22** from a first position wherein orifice **50** substantially aligns with orifice **30** to a second position wherein orifice **50** is misaligned with orifice **30** such that separator **48** blocks the passageway between bowl **22** and syringe body **52**. It is contemplated that separator **48** be rectangular, round, oval, oblong, square, polygonal, irregular, uniform, non-uniform, offset, staggered, tapered, consistent or variable, depending on the requirements of a particular application.

To facilitate movement of the bone cement through the passageway, a plunger **70** is provided. Plunger **70** is configured to push the bone cement into and through lumen **60**. Plunger **70** includes a proximal end **71** and a distal end **73**. Distal end **71** is configured as a curved or radiused button or knob. Proximal end **73** of plunger **70** includes a handle **72**. Plunger **70** is configured to fit through orifices **50** and **30** and slidably engages and extends through lumen **60** in syringe body **52** along central axis A towards distal end **58** of syringe body. Plunger **70** is sized for frictional engagement with inner surface **61** of lumen **60**. Handle **72** includes a flat surface **88** that facilitates apparatus resting on a surface of a table. It is contemplated that flat surface **88** be rectangular, round, oval, oblong, square, polygonal, irregular, uniform, non-uniform, offset, staggered, tapered, consistent or variable, depending on the requirements of a particular application. Bone cement can be highly viscous and therefore requiring a significant force to be pushed into syringe body **52**. After plunger **70** is inserted into orifices **50** and **30**, apparatus **20** can be flipped over to rest on handle **72**. By applying a downward force F on flanges **76**, plunger **70** pushes the bone cement through lumen **60** into dispense **80**.

To assist in holding apparatus **20** and for the protection of syringe body **52** a base **36** is attached to bowl **22**. Base **36** extends between a first end **42** and a second end **44**. Base **36** includes an inner surface **38** and an outer surface **40**. It is contemplated that base **36** be round, oval, oblong, square, rectangular, polygonal, irregular, uniform, non-uniform, offset, staggered, tapered, consistent or variable, depending on the requirements of a particular application. Inner surface **38** defines a cavity **46** configured for disposal of syringe body **52**. Base **36** is provided to allow the apparatus to stand upright on a surface without the end of the syringe body **52** touching the surface. Base **36** includes an opening **37** for viewing the syringe body **52** therein. In one embodiment, flanges **76** include a coupling portion **77** for attachment of base **36**.

For mixing the bone cement materials, a detachable spatula **74** is provided. Spatula **74** can be detachably attached to base **36**, mixing vessel **22** or other surface where practical.

In one embodiment, one or all of the components of the bone cement mixing apparatus are presented in a kit, such as for example, a disposable, peel-pack, pre-packed sterile devices. The kit can also be provided in a sterilized or in the alternative be provided in a sterilizable packaging. The kit includes, at least one of the following: syringe body, mixing vessel, separator, plunger, base and dispensing structures. The syringes and dispensing structures can be of various sizes, gauges and types depending on the particular applica-

tion. One or all of the components of the bone cement mixing apparatus may be reusable and sterilizable. The bone mixing apparatus may be configured as a kit with multiple sized and configured components.

In operation, bowl 22 is attached to syringe body 52. Separator 48 is moved to its second position, where orifice 50 is misaligned with orifice 30 of mixing vessel 22. Base 36 can be attached to provide an easier gripping surface for holding apparatus 20. Bone cement materials are placed inside bowl 22 and are mixed thoroughly with spatula 74. The approximate time of mixing is about 30 seconds. Once bone cement materials are thoroughly mixed, separator 48 is shifted to the first position where orifice 50 is aligned with orifice 30. Spatula 74 is used to push and guide bone cement mixture into syringe body 52. Time for this step is approximately 20-30 seconds. Plunger 70 is placed into syringe body 52 through orifices 50 and 30. Plunger 70 is pushed until the bone cement is close to opening 66. Apparatus 20 is flipped over so that handle 72 rests on table or other surface. If base 36 was attached, it can now be removed. A dispensing structure 80 is attached to proximal end 56 or syringe body 52. Apparatus 20 is now resting on handle 72 and a force F1 can be applied to flanges 76 to push bone cement material into dispensing structure 80. A plurality of dispensing structures 80 can be filled one after another as needed for the particular use. Apparatus 20 provides for quick transfer of the bone cement from bowl 22 to dispensing structure 80 thereby allowing for efficient use of time and bone cement. The present apparatus removes the step of having to pour the bone cement into the syringe body. The pouring of the cement allows for spills and wasted cement as well as inefficient use of time. The initial dose of bone cement into dispensing structure can be discarded as it may contain air bubbles.

It will be understood that various modifications may be made to the embodiments disclosed herein. Therefore, the above description should not be construed as limiting, but merely as exemplification of the various embodiments. Those skilled in the art will envision other modifications within the scope and spirit of the claims appended hereto.

What is claimed is:

1. A bone cement mixing apparatus comprising:
 - a mixing vessel for mixing bone cement materials having an orifice;
 - a syringe body having a proximal end, an oppositely disposed distal end, a longitudinal axis and a lumen extending from the proximal end to the distal end along the longitudinal axis, each of the proximal and distal ends having an opening therein, the opening in the proximal end configured to align with the orifice in the mixing vessel so as to provide a passageway between the mixing vessel and the lumen of the syringe body,
 - a separator having an orifice, the separator configured to slide between the proximal end of the syringe body and the mixing vessel from a first position wherein the orifice in the separator substantially aligns with the lumen in the syringe body and the orifice in the mixing vessel to a second position wherein the orifice in the separator is misaligned with the lumen in the syringe body and the orifice in the mixing vessel so as to block the passageway between the mixing vessel and the lumen of the syringe body, and
 - a plunger configured to extend through the orifice in the mixing vessel and into the lumen of the syringe body, the plunger being slideably movable along the longitudinal axis towards the distal end of the syringe body;
- wherein the orifice in the separator is coaxial with the longitudinal axis when the separator is in the first posi-

tion and the orifice in the separator is offset from the longitudinal axis when the separator is in the second position.

2. The bone cement mixing apparatus of claim 1 further comprising a base configured to fit around the syringe body and attach to the mixing vessel so that the mixing apparatus can stand upright on a surface without the distal end of the syringe body contacting the surface.

3. The bone cement mixing apparatus of claim 1 further comprising a spatula configured to fit within the mixing vessel for mixing and bone cement therein.

4. The bone cement mixing apparatus of claim 1 wherein the mixing vessel further comprises flanges that are connected to an outside surface of the mixing vessel and extend outwardly from the mixing vessel so as to provide an extended surface to apply downward pressure so as to advance the plunger into the passageway between the mixing vessel and the lumen of the syringe body.

5. The bone cement mixing apparatus of claim 1 wherein the distal end of the syringe body further comprises a coupling element configured to couple at least one dispensing structure to the syringe body.

6. The bone cement mixing apparatus of claim 5 wherein the at least one dispensing structure is a cannulated needle.

7. The bone cement mixing apparatus of claim 4 wherein the flanges further comprise a channel configured to accept the separator and provide a track for the separator to move from the first position to the second position.

8. The bone cement mixing apparatus of claim 4 further comprising a base configured to fit around the syringe body and attach to the mixing vessel so that the mixing apparatus can stand upright on a surface without the distal end of the syringe body contacting the surface wherein the flange further comprises a coupling portion adapted to removably attach the base to the flange.

9. A bone cement mixing kit comprising:
the bone cement mixing apparatus recited in claim 1;
at least one bone cement dispensing structure attachable to the bone cement mixing apparatus; and
a supply of bone cement for mixing in the bone cement mixing apparatus.

10. A method for mixing and dispensing bone cement comprising,

providing the bone cement mixing apparatus of claim 1;
moving the separator to the second position and adding bone cement to the mixing vessel;
mixing the bone cement in the mixing vessel;
moving the separator to the first position;
pushing and guiding the bone cement into the syringe body;
attaching a dispensing structure to the distal end of the syringe body; and
applying pressure on the plunger to advance the bone cement into the dispensing structure so as to produce a dispensing structure filled with bone cement.

11. A bone cement mixing apparatus comprising:
a mixing vessel for mixing bone cement materials having an orifice;
a syringe body having a proximal end, an oppositely disposed distal end, a longitudinal axis and a lumen extending along the longitudinal axis from the proximal end to the distal end, each of the proximal and distal ends having an opening therein, the opening in the proximal end configured to align with the orifice in the mixing vessel so as to provide a passageway between the mixing vessel and the lumen of the syringe body,

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a separator having an orifice, the separator configured to slide in opposite first and second directions along a transverse axis that extends perpendicular to the longitudinal axis between the proximal end of the syringe body and the mixing vessel from a first position wherein the orifice in the separator substantially aligns with the lumen in the syringe body and the orifice in the mixing vessel to a second position wherein the orifice in the separator is misaligned with the lumen in the syringe body and the orifice in the mixing vessel so as to block the passageway between the mixing vessel and the lumen of the syringe body,

a plunger configured to extend through the orifice in the mixing vessel and into the lumen of the syringe body, the plunger configured to slideably move along the longitudinal axis towards the distal end of the syringe body,

a base configured to fit around the syringe body and attach to the mixing vessel so that the mixing apparatus can stand upright on a surface without the distal end of the syringe body contacting the surface; and

a flange connected to an outside surface of the mixing vessel and extends outwardly from the mixing vessel so as to provide an extended surface to apply downward pressure to advance the plunger into the passageway between the mixing vessel and the lumen of the syringe; wherein the orifice in the separator is coaxial with the longitudinal axis when the separator is in the first position and the orifice in the separator is offset from the longitudinal axis when the separator is in the second position.

12. A bone cement mixing apparatus of claim **11** wherein the distal end of the syringe body further comprises a coupling element configured to couple at least one dispensing structure to the syringe body.

13. A bone cement mixing apparatus of claim **11** wherein the flange further comprises a coupling portion configured to removably attach the base to the flange so that the base fits

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around the syringe body and the mixing apparatus can stand upright on a surface without the distal end of the syringe body contacting the surface.

14. The bone cement mixing apparatus of claim **1** wherein the separator is configured to slide in opposite first and second directions along a transverse axis that extends perpendicular to the longitudinal axis.

15. The bone cement mixing apparatus of claim **1** wherein the plunger is slideably movable within the lumen along the longitudinal axis from the proximal end of the syringe body to the distal end of the syringe body.

16. The bone cement mixing apparatus of claim **1** wherein the separator is positioned between the orifice in the mixing vessel and the opening in the proximal end of the syringe body.

17. The bone cement mixing apparatus of claim **1** wherein the mixing vessel comprises a first end that includes the orifice in the mixing vessel and an opposite second end that includes a second orifice, the second orifice being permanently unobstructed.

18. The bone cement mixing apparatus of claim **1** further comprising a base that fits around the syringe body and attaches to the mixing vessel so that the mixing apparatus can stand upright on a surface without the distal end of the syringe body contacting the surface, the base comprising opposite first and second end surfaces that each include an opening extending therethrough, the openings of the base being coaxial with the lumen.

19. The bone cement mixing apparatus of claim **1** wherein the mixing vessel comprises a first end and an opposite second end that includes the orifice in the mixing vessel, the second end comprising flanges that are connected to an outside surface of the mixing vessel and extend outwardly from the mixing vessel, the flanges comprising a channel configured to accept the separator and provide a track for the separator to move from the first position to the second position, the channel extending perpendicular to the longitudinal axis.

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